

510(k) SUMMARY

K9410942

FEB 19 1997

1. COMPANY INFORMATION.

Name : Kretztechnik AG

Address : Tiefenbach 15
A-4871 Zipf, Austria

Telephone : 011-43-7682-2261-0

Contact Person (U.S.) : Jay C. Cone, President
Cone Instruments, Inc.
5201 Naiman Parkway
Solon, Ohio 44139
(216) 248-1035

Date Prepared : June 28, 1993 (Revised: February 18, 1994)

2. DEVICE NOMENCLATURE.

A. System.

Trade Name : COMBISON^R 530
(VOLUSON^R for volume scanning feature)

Common Name : Diagnostic Ultrasound Scanner

Classification Names : Ultrasonic Pulsed Echo Imaging System
Ultrasonic Pulsed Doppler Imaging System
Ultrasonic Obstetric-Gynecologic Imager

B. Transducers.

Trade Names : Sector Transducer Model No. AWP 3.5
Sector Transducer Model No. SWP 3.5
Sector Transducer Model No. VSW 3.5
Sector Transducer Model No. VSW 5.0
Sector Transducer Model No. VWP 3.5 B
Sector Transducer Model No. VWP 5.0
Sector Transducer Model No. VW 7/10
Transrectal Transducer Model No. VRW 77 AK
Transvaginal Transducer Model No. EW 5/7 K
Transvaginal Transducer Model No. VEW 7.5 R

Common Name : Mechanical Sector Ultrasound Imaging Transducer

Classification Name : Diagnostic Ultrasonic Transducer

Trade Names : Curved Linear Array Transducer Model ACA 3.5
Curved Linear Array Transducer Model ACA 5.0
Linear Array Transducer Model PLA 7.5

Common Name : Linear Array Ultrasound Imaging Transducer

Classification Name : Diagnostic Ultrasound Transducer

3. PREDICATE DEVICES.

- a. For Diagnostic Ultrasound Scanner COMBISON[®] 530:
Kretztechnik Diagnostic Ultrasound Scanner COMBISON[®] 330
Toshiba Diagnostic Ultrasound Scanner SSH-140A
Siemens Diagnostic Ultrasound Scanner SONOLINE SI-450
- b. For Sector Transducer AWP 3.5:
Previously cleared with COMBISON[®] 330 as Model AWP 3.5/A
- c. For Sector Transducer SWP 3.5:
Kretztechnik Sector Transducer AWP 3.5/A
Kretztechnik Sector Transducer AW 4/5 B/A
- d. For Sector Transducer VSW 3.5:
Kretztechnik Sector Transducer AWP 3.5/A
- e. For Sector Transducer VSW 5.0:
Kretztechnik Sector Transducer AWP 3.5/A
- f. For Sector Transducer VWP 3.5 B:
Kretztechnik Sector Transducer AWP 3.5/A
- g. For Sector Transducer VWP 5.0:
Kretztechnik Sector Transducer AWP 3.5/A
- h. For Sector Transducer VW 7/10:
Kretztechnik Sector Transducer NW 17.5 B/A
- i. For Transrectal Transducer VRW 77 AK:
Kretztechnik Transrectal Transducer VRW 177 AK/A
Kretztechnik Transrectal Transducer IRW 177 AK/A
- j. For Transvaginal Transducer EW 5/7 K:
Kretztechnik Transvaginal/Urologic Transducer WIW 17.5 AP/A
Kretztechnik Transvaginal Transducer IR 15/7 BG/A
- k. For Transvaginal Transducer VEW 7.5 R:
Kretztechnik Transvaginal/Urologic Transducer WIW 17.5 AP/A
Kretztechnik Transvaginal Transducer IR 15/7 BG/A
- l. For Curved Linear Array Transducer ACA 3.5:
Acoustic Imaging Convex Sector Transducer CLA 3.5
- m. For Curved Linear Array Transducer ACA 3.5:
Acoustic Imaging Convex Sector Transducer CLA 5.0
- n. For Linear Array Transducer PLA 7.5:
Acoustic Imaging Linear Array Transducer MLA 7.5

4. DEVICE DESCRIPTION.

- a. Scanner COMBISON[®] 530:
This device is intended to obtain and display B-scan and M-mode images as well as Pulsed Wave and Continuous Wave Doppler spectra, or Color Flow images. Additionally, the COMBISON[®] 530 offers the VOLUSON[®] 3D-scan system, which performs a number of B-scans, one adjacent to the other (only with special probes) and gives the user the possibility to visualize planes within the "volume" without the patient.
- b. Transducer AWP 3.5:
This device is a hand-held, annular array, mechanical sector probe intended for transcutaneous use with the COMBISON[®] 530 Diagnostic Ultrasound Scanner. The nominal operating frequency is 3.5 MHz. In B-mode the transducer operates as an end-firing sector probe over either of two selectable angle ranges (80°/60°). In M-mode and Pulsed Wave Doppler-mode the transducer is locked in one selectable position within the available sector angle ranges and operates as a stationary probe.
- c. Transducer SWP 3.5:
This device is a hand-held, annular array, mechanical sector probe intended for transcutaneous use with the COMBISON[®] 530 Diagnostic Ultrasound Scanner. The nominal operating frequency is 3.5 MHz. In B-mode the transducer operates as an end-firing sector probe over either of four selectable angle ranges (70°/60°/50°/40°). In M-mode and Pulsed Wave Doppler-mode the transducer is locked in one selectable position within the available sector angle ranges and operates as a stationary probe.
- d. Transducer VSW 3.5:
This device is a hand-held, annular array, mechanical sector probe intended for transcutaneous use with the COMBISON[®] 530 Diagnostic Ultrasound Scanner. The nominal operating frequency is 3.5 MHz. In B-mode the transducer operates as an end-firing sector probe over either of four selectable angle ranges (70°/60°/50°/40°). In M-mode and Pulsed Wave Doppler-mode the transducer is locked in one selectable position within the available sector angle ranges and operates as a stationary probe. With the COMBISON[®] 530 this transducer offers the possibility of an automated $\pm 30^\circ$ sweep of the scan plane. The transducer performs a number of B-scans, one adjacent to the other, to have a "volume" scanned.
- e. Transducer VSW 5.0:
This device is a hand-held, annular array, mechanical sector probe intended for transcutaneous use with the COMBISON[®] 530 Diagnostic Ultrasound Scanner. The nominal operating frequency is 5.0 MHz. In B-mode the transducer operates as an end-firing sector probe over either of four selectable angle ranges (70°/60°/50°/40°). In M-mode and Pulsed Wave Doppler-mode the transducer is locked in one selectable position within the available sector angle ranges and operates as a stationary probe. With the COMBISON[®] 530 this transducer offers the possibility of an automated $\pm 30^\circ$ sweep of the scan plane. The transducer performs a number of B-scans, one adjacent to the other, to have a "volume" scanned.

- f. Transducer VWP 3.5 B:
This device is a hand-held, annular array, mechanical sector probe intended for transcutaneous use with the COMBISON[®] 530 Diagnostic Ultrasound Scanner. The nominal operating frequency is 3.5 MHz. In B-mode the transducer operates as an end-firing sector probe over either of two selectable angle ranges (90°/60°). In M-mode and Pulsed Wave Doppler-mode the transducer is locked in one selectable position within the available sector angle ranges and operates as a stationary probe. With the COMBISON[®] 530 this transducer offers the possibility of an automated $\pm 15^\circ$ sweep of the scan plane. The transducer performs a number of B-scans, one adjacent to the other, to have a "volume" scanned.
- g. Transducer VWP 5.0:
This device is a hand-held, annular array, mechanical sector probe intended for transcutaneous use with the COMBISON[®] 530 Diagnostic Ultrasound Scanner. The nominal operating frequency is 5.0 MHz. In B-mode the transducer operates as an end-firing sector probe over either of two selectable angle ranges (90°/60°). In M-mode and Pulsed Wave Doppler-mode the transducer is locked in one selectable position within the available sector angle ranges and operates as a stationary probe. With the COMBISON[®] 530 this transducer offers the possibility of an automated $\pm 15^\circ$ sweep of the scan plane. The transducer performs a number of B-scans, one adjacent to the other, to have a "volume" scanned.
- h. Transducer VW 7/10:
This device is a hand-held, dual-element, mechanical sector probe intended for transcutaneous use with the COMBISON[®] 530 Diagnostic Ultrasound Scanner. The nominal operating frequencies are 7 and 10 MHz. In B-mode the transducer operates as an end-firing sector probe over either of two selectable angle ranges (90°/60°). In M-mode and Pulsed Wave Doppler-mode the transducer is locked in one selectable position within the available sector angle ranges and operates as a stationary probe. With the COMBISON[®] 530 this transducer offers the possibility of an automated $\pm 15^\circ$ sweep of the scan plane. The transducer performs a number of B-scans, one adjacent to the other, to have a "volume" scanned.
- i. Transducer VRW 77 AK:
This device is a hand-held, dual-element, mechanical sector probe intended for transrectal use with the COMBISON[®] 530 Diagnostic Ultrasound Scanner. The nominal operating frequency is 7.5 MHz. In B-mode the transducer operates as an end-firing sector probe over either of two selectable scan planes with different angle ranges (longitudinal angle range 100°; transversal angle range 350°). In Pulsed Wave Doppler-mode the transducer is locked in one selectable position within the available sector angle ranges and operates as a stationary probe. With the COMBISON[®] 530 this transducer offers the possibility of an automated $\pm 140^\circ$ sweep of the scan plane. The transducer performs a number of B-scans, one adjacent to the other, to have a "volume" scanned.
- j. Transducer EW 5/7 K:
This device is a hand-held, dual-element, mechanical sector probe intended for transvaginal use with the COMBISON[®] 530 Diagnostic Ultrasound Scanner. The nominal operating

frequencies are 5 and 7.5 MHz. In B-mode the transducer operates as an end-firing sector probe over either of two selectable angle ranges (130°/200°). In M-mode and Pulsed Wave Doppler-mode the transducer is locked in one selectable position within the available sector angle ranges and operates as a stationary probe.

k. Transducer VEW 7.5 R:

This device is a hand-held, single-element, mechanical sector probe intended for transvaginal use with the COMBISON[®] 530 Diagnostic Ultrasound Scanner. The nominal operating frequency is 7.5 MHz. In B-mode the transducer operates as an end-firing sector probe over an angle range of 100°. In M-mode and Pulsed Wave Doppler-mode the transducer is locked in one selectable position within the available sector angle range and operates as a stationary probe. With the COMBISON[®] 530 this transducer offers the possibility of an automated 180° rotation of the scan plane. The transducer performs a number of B-scans, one adjacent to the other, to have a "volume" scanned.

l. Transducer ACA 3.5:

This device is a hand-held, 128 element, curved linear array probe intended for transcutaneous use with the COMBISON[®] 530 Diagnostic Ultrasound Scanner. The nominal operating frequency is 3.5 MHz. In B-mode the transducer operates as an end-firing sector probe over an angle range of 58°. In M-mode and Pulsed Wave Doppler-mode specific element groups can be activated within the array and operate as a stationary probe.

m. Transducer ACA 5.0:

This device is a hand-held, 128 element, curved linear array probe intended for transcutaneous use with the COMBISON[®] 530 Diagnostic Ultrasound Scanner. The nominal operating frequency is 5.0 MHz. In B-mode the transducer operates as an end-firing sector probe over an angle range of 64°. In M-mode and Pulsed Wave Doppler-mode specific element groups can be activated within the array and operate as a stationary probe.

n. Transducer PLA 7.5:

This device is a hand-held, 128 element, linear array probe intended for transcutaneous use with the COMBISON[®] 530 Diagnostic Ultrasound Scanner. The nominal operating frequency is 7.5 MHz. In B-mode the transducer operates as an end-firing probe over a width of 55 mm. In M-mode and Pulsed Wave Doppler-mode specific element groups can be activated within the array and operate as a stationary probe.

5. INTENDED USES.

- a. Scanner COMBISON[®] 530:
This device is intended for use with the listed transducers for the transcutaneous, transrectal, and transvaginal imaging of organs or structures as an aid in the detection and assessment of physical and functional abnormalities using established diagnostic criteria; and in obstetric patients for the transcutaneous, or transvaginal imaging of the fetus and uterine structures including the performance of fetal measurements for the purpose of assessing fetal growth and maturity. The same clinical uses were recommended for predicate devices, COMBISON[®] 330, SSH-140A, and SONOLINE SI-450.
- b. Transducer AWP 3.5:
This device is intended for use with the COMBISON[®] 530 system for the transcutaneous imaging of intraabdominal organs and structures including the gastrointestinal tract, kidney, bladder, etc. as an aid in the detection and assessment of physical and functional abnormalities using established diagnostic criteria; and in obstetric patients for the transcutaneous imaging of the fetus and uterine structures including the performance of fetal measurements for the purpose of assessing fetal growth and maturity. The same clinical uses were recommended when this device was previously cleared with the COMBISON[®] 330.
- c. Transducer SWP 3.5:
This device is intended for use with the COMBISON[®] 530 system for the transcutaneous imaging of intraabdominal organs and structures including the gastrointestinal tract, kidney, bladder, etc. as an aid in the detection and assessment of physical and functional abnormalities using established diagnostic criteria; and in obstetric patients for the transcutaneous imaging of the fetus and uterine structures including the performance of fetal measurements for the purpose of assessing fetal growth and maturity. The same clinical uses were recommended for predicate devices AWP 3.5/A and AW 14/5 B/A.
- d. Transducer VSW 3.5:
This device is intended for use with the COMBISON[®] 530 system for the transcutaneous imaging of intraabdominal organs and structures including the gastrointestinal tract, kidney, bladder, etc. as an aid in the detection and assessment of physical and functional abnormalities using established diagnostic criteria; and in obstetric patients for the transcutaneous imaging of the fetus and uterine structures including the performance of fetal measurements for the purpose of assessing fetal growth and maturity. The same clinical uses were recommended for predicate device AWP 3.5/A.
- e. Transducer VSW 5.0:
This device is intended for use with the COMBISON[®] 530 system for the transcutaneous imaging of intraabdominal organs and structures including the gastrointestinal tract, kidney, bladder, etc. as an aid in the detection and assessment of physical and functional abnormalities using established diagnostic criteria; and in obstetric patients for the

transcutaneous imaging of the fetus and uterine structures including the performance of fetal measurements for the purpose of assessing fetal growth and maturity. The same clinical uses were recommended for predicate device AWP 3.5/A.

- f. Transducer VWP 3.5 B:
This device is intended for use with the COMBISON[®] 530 system for the transcutaneous imaging of intraabdominal organs and structures including the gastrointestinal tract, kidney, bladder, etc. as an aid in the detection and assessment of physical and functional abnormalities using established diagnostic criteria; and in obstetric patients for the transcutaneous imaging of the fetus and uterine structures including the performance of fetal measurements for the purpose of assessing fetal growth and maturity. The same clinical uses were recommended for predicate device AWP 3.5/A.
- g. Transducer VWP 5.0:
This device is intended for use with the COMBISON[®] 530 system for the transcutaneous imaging of intraabdominal organs and structures including the gastrointestinal tract, kidney, bladder, etc. as an aid in the detection and assessment of physical and functional abnormalities using established diagnostic criteria; and in obstetric patients for the transcutaneous imaging of the fetus and uterine structures including the performance of fetal measurements for the purpose of assessing fetal growth and maturity. The same clinical uses were recommended for predicate device AWP 3.5/A.
- h. Transducer VW 7/10:
This device is intended for use with the COMBISON[®] 530 system for the transcutaneous imaging of peripheral vessels and small organs including breast, thyroid, testes, etc. as an aid in the detection and assessment of physical and functional abnormalities using established diagnostic criteria. The same clinical uses were recommended for predicate device NW 17.5 BG/A.
- i. Transducer VRW 77 AK:
This device is intended for use with the COMBISON[®] 530 system for the transrectal imaging of the rectum and surrounding organs and structures including the rectum wall, prostate gland, etc. as an aid in the detection and assessment of physical and functional abnormalities using established diagnostic criteria. An approved biopsy attachment is available for use with this transducer. The same clinical uses were recommended for predicate device VRW 177 AK/A and IRW 177 AK/A.
- j. Transducer EW 5/7 K:
This device is intended for use with the COMBISON[®] 530 system in the imaging of the fetus and uterine structures utilizing the transvaginal approach as an aid in the diagnosis of obstetrical and gynecological conditions including the performance of fetal measurements for the purpose of assessing fetal growth and maturity. An approved biopsy attachment is available for use with this transducer. The same clinical uses were recommended for the predicate devices

WIW 17.5 AP/A and IR 15/7 BG/A.

- k. Transducer VEW 7.5 R:
This device is intended for use with the COMBISON[®] 530 system in the imaging of the fetus and uterine structures utilizing the transvaginal approach as an aid in the diagnosis of obstetrical and gynecological conditions including the performance of fetal measurements for the purpose of assessing fetal growth and maturity. An approved biopsy attachment is available for use with this transducer. The same clinical uses were recommended for the predicate devices WIW 17.5 AP/A and IR 15/7 BG/A.
- l. Transducer ACA 3.5:
This device is intended for use with the COMBISON[®] 530 system for the transcutaneous imaging of intraabdominal organs and structures including the gastrointestinal tract, kidney, bladder, etc. as an aid in the detection and assessment of physical and functional abnormalities using established diagnostic criteria; and in obstetric patients for the transcutaneous imaging of the fetus and uterine structures including the performance of fetal measurements for the purpose of assessing fetal growth and maturity. The same clinical uses were recommended for predicate device CLA 3.5.
- m. Transducer ACA 5.0:
This device is intended for use with the COMBISON[®] 530 system for the transcutaneous imaging of intraabdominal organs and structures including the gastrointestinal tract, kidney, bladder, etc. as an aid in the detection and assessment of physical and functional abnormalities using established diagnostic criteria; and in obstetric patients for the transcutaneous imaging of the fetus and uterine structures including the performance of fetal measurements for the purpose of assessing fetal growth and maturity. The same clinical uses were recommended for predicate device CLA 5.0.
- n. Transducer PLA 7.5:
This device is intended for use with the COMBISON[®] 530 system for the transcutaneous imaging of peripheral vessels and small organs including breast, thyroid, testes, etc. as an aid in the detection and assessment of physical and functional abnormalities using established diagnostic criteria. The same clinical uses were recommended for predicate device MLA 7.5.

6. COMPARISON WITH PREDICATE DEVICES(S).

a. Scanner COMBISON[®] 530:

This scanner is capable of B-, M-, Pulsed Wave and Continuous Wave Doppler, and Color Flow Mapping Modes. The predicate scanner COMBISON[®] 330 is only capable of B- and M-Mode, while the Siemens SONOLINE SI-450 scanner also includes Pulsed Wave and Continuous Wave Doppler, and the Toshiba SSH-140A offers Color Flow Mapping in addition. The COMBISON[®] 530 volume-scanning feature is an extension of the cine-loop storage/retrieval capability found in all three predicate devices.

b. Transducer AWP 3.5:

This transducer was already approved for use with the scanner COMBISON[®] 330. There has been no change performed to the original version. Safety and effectiveness are not affected.

c. Transducer SWP 3.5:

This transducer differs from the predicate device only in minor respects; none of these minor differences adversely effects safety or effectiveness. The nominal frequency of both transducers is 3.5 MHz and both utilize a mechanically sectorized annular array; a three-phase motor is used to provide the rocking motion in transducer SWP 3.5, a stepper motor in the AWP 3.5/A. Both have similar sector angle ranges--70°, 60°, 50°, or 40° selectable in the case of the SWP 3.5, 80° fixed in the case of AWP 3.5/A.

Both of the patient contact materials utilized in transducer SWP 3.5 (UDEL[®] polysulphone and TPX) have been employed in the previously marketed transducer AWP 3.5/A.

d. Transducer VSW 3.5:

This transducer differs from the predicate device only in minor respects; none of these minor differences adversely effects safety or effectiveness. The nominal frequency of both transducers is 3.5 MHz and both utilize a mechanically sectorized annular array; a three-phase motor is used to provide the rocking motion in transducer VSW 3.5, a stepper motor in the AWP 3.5/A. Both have similar sector angle ranges--70°, 60°, 50°, or 40° selectable in the case of the SWP 3.5, 80° fixed in the case of AWP 3.5/A.

The VSW 3.5 is also able to move the B-scan plane to obtain a VOL-scan.

Both of the patient contact materials utilized in transducer VSW 3.5 (LUCALEN[®] and ULTRADUR[®]) have been employed in food-, drug-, and cosmetics packaging.

e. Transducer VSW 5.0:

This transducer differs from the predicate device only in minor respects; none of these minor differences adversely effects safety or effectiveness. The nominal operating frequency of the VSW 5.0 is 5.0 MHz, while, for transducer AWP 3.5/A, the nominal frequency is 3.5 MHz. Both utilize a mechanically sectorized annular array; a three-phase motor is used to provide the rocking motion in transducer VSW 5.0, a stepper motor in the AWP 3.5/A. Both have similar sector angle ranges--70°, 60°, 50°, or 40° selectable in the case of the SWP 3.5, 80° fixed in the case of AWP 3.5/A.

The VSW 3.5 is also able to move the B-scan plane to obtain a VOL-scan.

Both of the patient contact materials utilized in transducer VSW 5.0 (LUCALEN[®] and ULTRADUR[®]) have been employed in food-, drug-, and cosmetics packaging.

f. Transducer VWP 3.5 B:

This transducer differs from the predicate device only in minor respects; none of these minor differences adversely effects safety or effectiveness. The nominal frequency of both transducers is 3.5 MHz and both utilize a mechanically sectorized annular array; a stepper motor is used to provide the rocking motion in both transducers. Both have similar sector angle ranges--90°, 60° selectable in the case of the VWP 3.5 B, 80° fixed in the case of AWP 3.5/A.

The VWP 3.5 B is also able to move the B-scan plane to obtain a VOL-scan.

Both of the patient contact materials utilized in transducer VWP 3.5 B (LUCALEN[®] and ULTRADUR[®]) have been employed in food-, drug-, and cosmetics packaging.

g. Transducer VWP 5.0:

This transducer differs from the predicate device only in minor respects; none of these minor differences adversely effects safety or effectiveness. The nominal operating frequency of the VWP 5.0 is 5.0 MHz, while, for transducer AWP 3.5/A, the nominal frequency is 3.5 MHz. Both utilize a mechanically sectorized annular array; a stepper motor is used to provide the rocking motion in both transducers. Both have similar sector angle ranges--90°, 60° selectable in the case of the VWP 5.0, 80° fixed in the case of AWP 3.5/A.

The VWP 5.0 is also able to move the B-scan plane to obtain a VOL-scan.

Both of the patient contact materials utilized in transducer VWP 5.0 (LUCALEN[®] and ULTRADUR[®]) have been employed in food-, drug-, and cosmetics packaging.

h. Transducer VW 7/10:

This transducer differs from the predicate device only in minor respects; none of these minor differences adversely effects safety or effectiveness. The nominal operating frequencies of the VW 7/10 are 7.5 and 10 MHz, while, for transducer NW 17.5 B/A, the nominal frequency is only 7.5 MHz. Both utilize a mechanically sectorized single-element; a stepper motor is used to provide the rocking motion in both transducers. Both have similar sector angle ranges--110°, 80° selectable in the case of the VW 7/10, 80° fixed in the case of NW 17.5 B/A.

The VW 7/10 is also able to move the B-scan plane to obtain a VOL-scan.

Both of the patient contact materials utilized in transducer VW 7/10 (LUCALEN[®] and ULTRADUR[®]) have been employed in food-, drug-, and cosmetics packaging.

i. Transducer VRW 77 AK:

This transducer differs from the predicate device only in minor respects; none of these minor differences adversely

effects safety or effectiveness. The only difference between the transducer VRW 77 AK and the predicate transducer VRW 177 AK/A is the longitudinal scan angle range, which is 100° in case of the VRW 77 AK transducer and 90° in case of the predicate transducer VRW 177 AK/A.

Both of the patient contact materials utilized in transducer VRW 77 AK have been employed in the previously marketed transducers AWP 3.5/A and VRW 177 AK/A.

j. Transducer EW 5/7 K:

This transducer differs from the predicate transducers only in minor respects; none of these minor differences adversely affect safety or effectiveness. Transvaginal transducer EW 5/7 K offers selectable nominal operating frequencies of 5.0 and 7.5 MHz. Predicate transducer IR15/7BG/A operated at a fixed nominal frequency of 5.0 MHz, while transducer WIW17.5AP/A operated at a fixed nominal frequency of 7.5 MHz. Mechanical sectoring of the two elements in transducer EW 5/7 K is accomplished by means of a rope drive; mechanical sectoring of both transducer IR15/7BG/A and transducer WIW17.5AP/A is accomplished using a cogwheel gear mechanism. Transducer EW 5/7 K offers two selectable sector angle ranges (130° or 200°). The sector angle range of transducer IR15/7BG/A was fixed at 240°; the sector angle range of WIW17.5AP/A was fixed at 118°.

Both of the patient contact materials utilized in transducer EW 5/7 K (TPX and UDEL[®] polysulphone) have been employed in previously marketed transducers--TPX in transducer IR15/7BG/A and WIW17.5AP/A, and UDEL[®] polysulphone in sector transducer AWP3.5/A.

k. Transducer VEW 7.5:

This transducer differs from the predicate transducers only in minor respects; none of these minor differences adversely affect safety or effectiveness. Transvaginal transducer VEW 7.5 R offers a nominal operating frequency of 7.5 MHz. Predicate transducer IR15/7BG/A operated at a fixed nominal frequency of 5.0 MHz, while transducer WIW17.5AP/A operated at a fixed nominal frequency of 7.5 MHz. Mechanical sectoring of the single element in transducer VEW 7.5 R is accomplished by means of a rope drive; mechanical sectoring of both transducer IR15/7BG/A and transducer WIW17.5AP/A is accomplished using a cogwheel gear mechanism. Transducer VEW 7.5 R offers a sector angle range of 100°. The sector angle range of transducer IR15/7BG/A was fixed at 240°; the sector angle range of WIW17.5AP/A was fixed at 118°. The VEW 7.5 R is also able to rotate the B-scan plane 180°. (Combined motion in case of VOL-scan.)

Each of the patient contact materials utilized in transducer VEW 7.5 R (TPX and ULTRADUR[®]/ABS) have been employed in previously marketed transducers--TPX in transducer IR15/7BG/A and WIW17.5AP/A. ULTRADUR[®]/ABS is widely used for food-, drug-, and cosmetics packaging.

l. Transducer ACA 3.5:

This transducer differs from the predicate transducers in no respects adversely affecting safety or effectiveness. The ACA 3.5 type transducer is manufactured and also marketed by

Acoustic Imaging as model CLA 3.5 (Kretztechnik is an OEM customer of Acoustic Imaging).

m. Transducer ACA 5.0:

This transducer differs from the predicate transducers in no respects adversely affecting safety or effectiveness. The ACA 5.0 type transducer is manufactured and also marketed by Acoustic Imaging as model CLA 5.0 (Kretztechnik is an OEM customer of Acoustic Imaging).

n. Transducer PLA 7.5:

This transducer differs from the predicate transducers in no respects adversely affecting safety or effectiveness. The PLA 7.5 type transducer is manufactured and also marketed by Acoustic Imaging as MLA 7.5 (Kretztechnik is an OEM customer of Acoustic Imaging).

7. PERFORMANCE DATA.

- a. Nature of Data Submitted: Appropriate nonclinical tests as described below have been performed to assess pertinent performance variables. Formal clinical studies were not conducted because the scanner COMBISON[®] 530, as well as the listed transducers, do not raise new questions concerning safety or effectiveness when compared with predicate devices.
- b. Electrical Safety: Tests utilizing the listed transducers with COMBISON[®] 530 scanner were performed to measured electrical leakage currents according to IEC Standard 601.1. Guard wire resistance and the following leakage currents: (1) ground, (2) housing, (3) patient device, and (4) mains voltage at patient device were measured and found to be well within the limits for Class 1, Type BF devices established by IEC Standard 601.1.
- c. Imaging Performance: Performance characteristics including gain, depth compensation, magnification, frame rate, image orientation, measurement accuracy, sector angle, and noise level for each possible operating mode were tested using appropriate phantoms under the Kretztechnik AG Transducer-Software Check Protocol. All performance values were found to be within the limits stated in product specifications.
- d. Acoustic Output: The maximum acoustic output for each transducer and each operating mode was measured under worst-case conditions and documented according to TRACK III reporting procedures as described in FDA guidelines. Results, expressed as derated values to account for assumed attenuation in tissue, were as follows:

TRANSDUCER	NOMINAL FREQUENCY	MODE	I_{SPTA} (mW/cm ²)	I_{SPPA} (W/cm ²)
AWP 3.5	3.5 MHz	B-Mode	26.40	101.65
		M-Mode	49.00	102.00
		PW-Mode	574.00	30.00
SWP 3.5	3.5 MHz	B-Mode	10.90	145.88
		M-Mode	58.00	146.00
		PW-Mode	458.00	27.00
VSW 3.5	3.5 MHz	B-Mode	20.40	159.26
		M-Mode	65.00	159.00
		PW-Mode	676.00	21.00
		VOL-Mode	2.00	159.26
VSW 5.0	5.0 MHz	B-Mode	9.80	171.74
		M-Mode	60.00	172.00
		PW-Mode	543.00	27.00
		VOL-Mode	0.40	171.74

TRANSDUCER	NOMINAL FREQUENCY	MODE	I_{SPTA} (mW/cm ²)	I_{SPTA} (W/cm ²)
VWP 3.5 B	3.5 MHz	B-Mode	46.30	159.26
		M-Mode	65.00	159.00
		PW-Mode	676.00	21.00
		VOL-Mode	5.10	159.26
VWP 5.0	5.0 MHz	B-Mode	15.50	171.74
		M-Mode	60.00	172.00
		PW-Mode	396.00	22.00
		VOL-Mode	1.10	171.74
VW 7/10	7.5 MHz	B-Mode	9.00	170.36
		M-Mode	43.00	170.00
		PW-Mode	463.00	85.00
		VOL-Mode	0.60	170.36
	10 MHz	B-Mode	6.00	163.14
		M-Mode	31.00	163.00
		PW-Mode	463.00	85.00
		VOL-Mode	0.30	163.14
EW 5/7 K	5.0 MHz	B-Mode	5.40	67.84
		M-Mode	31.00	68.00
		PW-Mode	550.00	29.00
	7.5 MHz	B-Mode	5.40	145.12
		M-Mode	32.00	145.00
		PW-Mode	3.90	20.00
VEW 7.5 R	7.5 MHz	B-Mode	3.80	140.25
		M-Mode	20.00	140.00
		PW-Mode	355.00	29.00
		VOL-Mode	3.80	140.25
VRW 77 AK	7.5 MHz	B-Mode	7.80	137.51
		M-Mode	34.00	138.00
		PW-Mode	474.00	101.00
		VOL-Mode	0.50	164.97
ACA 3.5	3.5 MHz	B-Mode	3.50	50.80
		M-Mode	19.00	51.00
		PW-Mode	431.00	15.00
		CFM-Mode	564.60	61.30

TRANSDUCER	NOMINAL FREQUENCY	MODE	I_{SPTA} (mW/cm ²)	I_{SPPA} (W/cm ²)
ACA 5.0	5.0 MHz	B-Mode	6.90	65.30
		M-Mode	24.00	102.00
		PW-Mode	427.00	16.00
		CFM-Mode	685.70	118.20
PLA 7.5	7.5 MHz	B-Mode	3.50	77.40
		M-Mode	9.00	77.00
		PW-Mode	429.00	89.00
		CFM-Mode	703.30	70.00

All values obtained for the listed transducers during acoustic output testing were lower than the officially published maxima for previously approved devices for the same intended uses. Since the reported acoustic output values for all transducers listed in Section 3 as predicate devices were also lower than the established limits, the test data indicate substantial equivalence with respect to the acoustic output.

- e. Conclusions: Nonclinical performance testing of the scanner COMBISON[®] 530 and the listed transducers has been performed, and the results demonstrate that these devices are safe, effective, and perform as well or better than the legally marketed devices with which this scanner and these transducers have been compared.